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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/291,227	04/13/1999	MICHAEL G. HAYEK	IAM467PA	1823
27752	7590	06/07/2004	EXAMINER	
THE PROCTER & GAMBLE COMPANY INTELLECTUAL PROPERTY DIVISION WINTON HILL TECHNICAL CENTER - BOX 161 6110 CENTER HILL AVENUE CINCINNATI, OH 45224			WANG, SHENGJUN	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 06/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/291,227	Applicant(s) HAYEK, MICHAEL G.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 27, 2004 has been entered.

Claim Rejections 35 U.S.C. 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 3-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of "which is subjected to ordinary condition" in claims 1, 9 and 11 lack support from the specification or claims as originally filed. Applicants fail to provide proper written description as to the subject matter encompassed by such limitation.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 3-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. The term "ordinary " in claims 1, 9 and 11 is a relative term which renders the claim indefinite. The term "ordinary" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claims are indefinite as to the dogs and cats encompassed thereby.

Claim Rejections 35 U.S.C. § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 3-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. (US Patent 5,937,790, of record).

9. Ito teaches a method of reducing stress in animals, including cats and dogs, by administering to the animals a composition comprising antioxidant selected from carotene and lutein etc. the antioxidant is in the concentration of about 0.02%. See, particularly, column 5, lines 16-20, 40-45, table 1 in column 8, and claims 15-16. Note, it is well known in the art that stress reduces the immunity. (see column 1, lines 23-26). Ito noted that domestic animals such as dogs and cats are inevitable subject to stress, because of the restricted living space (preventing from running off). See, column 1, lines 33-40.

10. Ito et al. does not teach expressly to choose lutein as the active ingredients, or particularly employ the lutein containing feed for immune enhancing purpose.

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However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ lutein as the antioxidants in Ito's method since Lutein is one of the eight disclosed species (column 5, line 17-20), and is one of the preferred species (table 1 in column 8). The employment of lutein is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388). Further the reduction of stress certainly enhance the immunity since stress is known to reduce the immunity. As to the amounts of lutein specified herein 1-50 mg/day, note a dog or cat feed 5 to 250 grams/day of the feed disclosed by Ito (contains 0.2% of antioxidants) would meet this limitation.

11. As to claims 9-11, reciting particular function of the process, note the function limitation in the preamble is generally not accorded any patentable weight where it merely recites the purpose of the process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). With respect to the newly added limitation about the dogs and cats, "which is subjected to ordinary condition," note being subject to stress condition, e.g., being keep from running off, is considered "an ordinary condition" for domestic dogs and cats.

12. Claims 1, 3-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. (US Patent 5,937,790) in view of Jyonouchi et al. (IDS, March 22, 2002) in view of Anon (IDS, March 22, 2002), and Krinsky (IDS, March 22, 2002), and further in view of CRC Handbook of Toxicology (of record) for reasons set forth in the prior office action.

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13. Ito et al. teach a animal feed comprising antioxidant selected from carotene and lutein etc. the antioxidant is in the concentration of about 0.02%. Ito further teaches method for reducing stress in animal comprising feeding the animal (including dog and cat) with the antioxidant agent. See, particularly, column 5, lines 16-20, and claims 8-16. Ito also teaches that the usefulness of carotenoids as food additive is for a broad range of animals including mammals and fish. See, particularly, column 6, lines 8-11. It is also known in the art that stress inducing reduction of immunity. Ito noted that domestic animals such as dogs and cats are inevitable subject to stress, because of the restricted living space (preventing from running off). See, column 1, lines 33-40.

14. Ito et al. does not teach expressly to choose lutein as the active ingredients, or particularly employ the lutein containing feed for immune enhancing purpose.

15. However, Jyonouchi et al teaches that carotenoids in general, and lutein in particular, as antioxidants, are known to be useful in enhancing immune response animals. See the abstract, and the discussion. Anon teaches an ailment specific dietary supplements comprising lutein, which may be useful for enhancing immune response. See, the whole article. Krinsky teaches that it is well known that carotenoids have effect of immune enhancement in animals. See the abstract, and the summary. The CRC Handbook of Toxicology, 1995, at page 11 describes the fact that experimental animal models are known to be useful in condition that mimic human disease.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ Ito's feed with lutein as the antioxidant, to feed cat or dog for enhancing their immune systems.

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A person of ordinary skill in the art would have been motivated to employ Ito's feed with lutein as the antioxidant, to feed cat or dog for enhancing their immune systems because lutein is known to be useful for enhancing the immune system of animals, and is known to be useful in dog or cat feed. As to the amounts of lutein specified herein 1-50 mg/day, note a dog or cat feed 5 to 250 grams/day of the feed disclosed by Ito (contains 0.2% of antioxidants) would meet this limitation.

16. As to claims 9-11, reciting particular function of the process, note the function limitation in the preamble is generally not accorded any patentable weight where it merely recites the purpose of the process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). With respect to the newly added limitation about the dogs and cats, "which is subjected to ordinary condition," note being subject to stress condition, e.g., being keep from running off, is considered "an ordinary condition" for domestic dogs and cats.

Response to the Arguments

Applicants' amendments and remarks submitted February 27, 2004 have been fully considered, but are not persuasive for reasons discussed below.

With respect to the newly added limitation, "which is subjected to ordinary conditions," see the discussion above. Particularly, Ito's stress conditions would include "ordinary

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conditions” of dogs and cats. Further, Ito disclosed feed for dogs and cats without any limitation as to the condition of dogs or cats. See the claims.

17. In response to applicant’s arguments that Ito does not teaches the usefulness of lutein as anti-stress agent or as therapeutical agents, it is noted the instant claims are directed to effecting a biochemical pathway with an old and well known compounds. The argument that such claims are not directed to the old and well known ultimate utility (food additive) for the compounds, e.g., lutein, are not probative. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant’s attention is directed to *In re Swinehart*, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated “is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.” The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

18. As to the rejections over Ito in view of Jyonouchi et al. Anon, Krinsky and CRC Handbook or Toxicology, applicants contend that the examiner did not consider the as a whole, and ingored the “gist” or “thrust” of the invention, the examiner disagrees. The claimed invention read on feeding dog or cat with a composition comprising lutein, wherein lutein is in an amount of 1-50 mg/day. As discussed above, such method has been fairly suggested. The examiner respectfully submits that it is applicants who have not considered the cited references as a whole, but have focused on very specific examples in cited references. For example, Jyonouchi teaches that carotenoids in general, and lutein in particular, as antioxidants, are known

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to be useful in enhancing immune response of animals. Jyonouchi never teach or suggest the usefulness of enhancing immune response is limited only to intraperitoneal injection to mice. Taking the cited references as a whole, one of ordinary skill in the art would have been motivated to feed dogs or cats with a composition comprising lutein, particularly for enhancing immune response.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang

May 30, 2004